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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/726,066	12/02/2003	Martin Zimmerling	1941/172	2565
2101	7590	08/25/2006	EXAMINER	
BROMBERG & SUNSTEIN LLP 125 SUMMER STREET BOSTON, MA 02110-1618			KOHARSKI, CHRISTOPHER	
			ART UNIT	PAPER NUMBER
			3763	

DATE MAILED: 08/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/726,066

Applicant(s)

ZIMMERLING ET AL.

Examiner

Christopher D. Koharski

Art Unit

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 May 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 6-32 and 34 is/are pending in the application.
- 4a) Of the above claim(s) 7, 8, 18, 19, 23-25, 27, 28, 31 and 32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 6, 9-17, 20-22, 26, 29, 30 and 34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

Examiner acknowledges amended claims 1, 4, 21, 29 and new claim 34. Currently claims 1-4, 6-32 and 34 are currently pending in this application with claims 7-8, 18-19, 23-25, 27-28, and 31-32 withdrawn (from a previous restriction election filed 12/27/2005) leaving claims 1-4, 6, 9, 9-17, 20-22, 26, 29, 30 and 34 pending for examination. For response to Applicant's Remarks filed 5/1/2006 see response to arguments below.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 6, 9-13, 20-21, 26 and 29-30 rejected under 35 U.S.C. 102(b) as being anticipated by Negre (5,643,194). Negre discloses a subcutaneous valve and device for externally setting it.

Regarding claims 1-4, 6, 9-13, 20-21, 26 and 29-30, Negre discloses a subcutaneous implant system comprising a fluid chamber having an inlet (6) and outlet (7) with an internal magnet (12,13) disposed within the fluid chamber with the magnetic elements being able to move in a rotational motion and a positional displacement (Figures 1-2). An external magnetic device (17) is provided for setting and flow control the implanted device through the skin (col 2, ln 44-53) wherein the device is rotatable.

Art Unit: 3763

The device of Negre is capable of being (col 1, 59-62; col 6, ln 65-67 and col 7, ln 1-2) implanted and used in many intervening medical functions and is capable of being used with a cochlear implant. The system is designed to be implanted and inherently this is composed of various plastics (col 1, ln 59) and is inherently biocompatible to facilitate internal implantation without rejection. There are various internal magnetic components that are multiple cylindrical and spherical shapes (Figures 1-2).

Claim Rejections - 35 USC § 102

Claim 34 is rejected under 35 U.S.C. 102(b) as being anticipated by Loe (3,371,670) or Bucalo (3,777,737). Loe discloses a fluid control bi-stable magnetic duct valve while Bucalo discloses a device and method for reversibly interrupting fluid flow.

Regarding claim 34, Loe discloses a fluid chamber with an inlet and outlet with an internal magnet that is capable of restricting the fluid flow (Figure 1) without a spring while Bucalo also discloses a fluid chamber with an inlet and outlet with an internal magnet that is capable of restricting the fluid flow without a spring (Figures 12-13).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

Art Unit: 3763

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 21-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Negre in view of Rehder et al (USPUBN 2002/01 08623). Negre meets the claim limitation as described above but fails to include an external indicator including a compass.

However, Rehder discloses an external indicator for use with an implantable magnetically actuated device (Figure 2).

At the time of the invention, it would have been obvious to incorporate the external indicator of Rehder into the invention of Negre. The motivation would have been in order to locate the device for ease of removal if the device is defective and needs to be replaced (see summary of Rehder).

The references are analogous in the art and with the instant invention; therefore, a combination is proper. Therefore, one skilled in the art would have combined the teachings in the references in light of the disclosure of Rehder.

Claim Rejections - 35 USC § 103

Claims 14-17 are rejected under 35 U.S.C 103(a) as being unpatentable over Negre. Negre meets the claim limitations as described above except for various biocompatible coatings.

Regarding claims 14-17, it would have been obvious to one having ordinary skill in the art at the time the invention was made to coat the various internal parts to

facilitate biocompatibility, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as (such as internal implantation, of which silicone is well-known biocompatible material) a matter of obvious design choice. *In re Leshin*, 227 F.2d 197, 125 USPQ 416 (CCPA 1960).

Response to Arguments

Applicant's arguments with respect to claims 1-4, 6, 9-17, 20-22, 26 and 29-30 regarding the Prosl et al. (4,541,429) and Marion (4,443,214) references have been considered but are moot in view of the new ground(s) of rejection necessitated by Applicant's amendments to independent claims 1 and 29.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

Art Unit: 3763

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher D. Koharski whose telephone number is 571-272-7230. The examiner can normally be reached on 7:30am to 4:00pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Date: 8/21/02


Christopher D. Koharski
AU 3763


NICHOLAS D. LUCCHESI
SUPERVISOR
TECHNICAL CENTER 3700